

REMARKS

I. Amendment

In this response, claim 1 has been amended to include the subject matter of claim 25 as originally filed. This change necessitated cancellation of claim 25.

New claims 50-53 have been added. These new claims add no new matter to the specification. Support for claim 50 may be found in claim 6 as originally filed. Support for claim 50 may also be found in the Examples such as Example 1 (Sec. 4); Example 2 (Sec. 6); Example 3 (Sec. 4); Example 4 (Sec. 5); Example 5 (Sec. 5); Example 6 (Sec. 5); Example 7 (Sec. 5); Example 8 (Sec. 5) and Example 9 (Sec. 4).

Support for claims 51-53 may be found in claims 26-28 as originally filed.

The amendment adds no new matter to the specification. Support for the amendment may be found in the specification as originally filed.

II. Request for Consideration of a Previously Submitted Supplemental Information Disclosure Statement

On June 17, 2004 Applicants submitted a Supplemental Information Disclosure Statement and PTO-1449 to disclose two references. The Information Disclosure Statement was mailed out after the Examiner issued the Office Action, but before Applicants received it. Applicants respectfully request the Examiner's consideration and acknowledgement of the Supplemental Information Disclosure Statement.

III. Discussion of the Rejection under 35 U.S.C. Sec. 102(e) over Lundberg

Claims 1-3, 5, 7, 9, 11, 12, 15-19, 21, 22, 29 and 31 have been rejected under 35 U.S.C. Sec. 102(e) as allegedly anticipated by Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection.

By this amendment, Applicants have included the subject matter of claim 25 in independent claim 1. The Examiner did not find claim 25 to be anticipated by the cited reference. Therefore, the cited reference does not anticipate Applicants' invention as set forth in claim 1 as amended.

Claims 2, 3, 5, 7, 9, 11, 12, 15-19, 21, 22, 29 and 31 depend on claim 1. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference for the reason provided above.

Therefore Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 102(e) over Lundberg.

IV. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg

Claims 1-3, 5, 7, 9, 11-19, 21-29 and 31 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection.

As Applicants indicated in their previous response, the tablets of the '770 patent dissolve in a glass of water, not in a patients' mouth. Those skilled in the art understand this, and would not look to a reference directed to effervescent tablets for direction when contemplating creation of tablets for oral dissolution. This is so because an effervescent tablet will be dissolved in a large amount of water, while an orally disintegrable tablet will be dissolved in only a minimal amount of water (saliva).

The Examiner does not appear to understand this fact, and has insisted that "the burden is shifted to applicant to provide a side-by-side data showing the effervescent tablet taught by Lundberg does not dissolve in a patient's mouth in less than 1 minute".

To satisfy the Examiner, Applicants have provided a Declaration which accompanies this response. In the Declaration, Applicants have calculated the amount of CO₂ which would be evolved in the unlikely event that the tablets of Lundberg were ingested orally. In the Declaration, Mr. Shimizu has calculated the amount of CO₂ which would be evolved from the tablets formed in Lundberg's Examples 1 and 3-6. The amount of CO₂ which would be evolved in a patient's mouth would be from 100-300 ml. (should the patient directly ingest an effervescent tablet). This is a very large amount of CO₂; an amount which would be prohibitively uncomfortable to a patient ingesting an effervescent tablet orally.

To prove to the Examiner that this is so, an experiment with human volunteers was performed. The volunteers tested effervescent constituents wherein from 10-100 ml CO₂ would be evolved in the oral cavity, to see what amount of CO₂ they could tolerate. In the test, every volunteer indicated that constituents effervescing 100 ml of CO₂ directly in the mouth were intolerable. This amount of CO₂ is less than the amount calculated to be released from tablets of Lundberg's Example 1; which would theoretically evolve the lowest amount of CO₂ of the exemplified Lundberg effervescent tablets. The other examples of the cited art would evolve even three times more CO₂ in the oral cavity. Effervescent tablets such as those of the cited art which cause such a large amount of CO₂ to be released in the mouth would definitely be too uncomfortable to ingest orally.

In fact, the volunteers found that constituents from which as little as 20 ml of CO₂ evolved in the mouth to be intolerable. It is quite clear that the Lundberg effervescent tablets cannot be administered directly into the mouth. They are meant to be dissolved in water.

Independent claim 1 recites orally disintegrable tablets. The tablets of the cited art are not orally disintegrable, as the amount of effervescence they produce when administered in the mouth is intolerable. Therefore, the cited reference does not teach or suggest Applicants' invention as set forth in claim 1 as amended.

Claims 25-28 have been cancelled. Claims 2, 3, 7, 9, 11-19, 21-24, 29 and 31 depend on claim 1. Applicants submit that the more specific dependent claims are also not rendered obvious by the cited reference for the reason provided above.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Lundberg.

V. Conclusion

Reconsideration and allowance of the claims is requested in light of the arguments provided above. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: October 15, 2004

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh
Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293
Attorney for Applicants
Customer No. 23,115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date October 15, 2004.

Express Mail Label No. EV 524906098 US

Gail L. Winokur
Printed Name: Gail L. Winokur